CLIA BITS

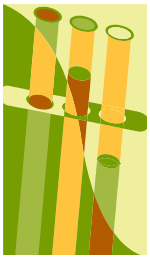
North Dakota Department *of* Health
Division *of* Health Facilities
Winter 2004

New Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services

By now you have probably heard the news, but if not, here it is: the new Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, is now available and in effect. The new Appendix C became available on the Centers for Medicare and Medicaid Services (CMS) website Jan. 12, 2004. The national implementation date for the new laboratory survey process also became effective the same day.

For the most part, this final rule simply reorganizes portions of the prior CLIA regulations. The regulations now are arranged to match the path a patient specimen takes as it moves through the laboratory – preanalytic, analytic and postanalytic.

The previous subparts J, K and P have been combined into two new subparts: Subpart J — Facility Administration for Nonwaived Testing, and Subpart K— Quality System for Nonwaived Testing. The provisions outlined in Subpart K — Quality Systems for Nonwaived Testing at section 493.1250, analytic systems requirements, now apply to all laboratories performing nonwaived testing. Prior to this rule, laboratories that performed moderate complexity tests using an instrument, kit or test system cleared by the Food and Drug Administration through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use were not held to all of these requirements.



CMS is focusing on an educational approach and the continued use of the outcome-oriented survey process. This means that each CMS surveyed laboratory will have one educational survey. This gives laboratories time (about two years) and the opportunity to receive the technical assistance that may be needed to meet the updated requirements.

The new interpretive guidelines and additional information are available at: www.cms.hhs.gov/clia.

Inside this issue:

Special points of interest:

- New survey procedure and interpretive guidelines
- Learn what the most commonly cited issues are.
- NCCLS publishes a revised order of draw.

Most Commonly Cited Issues

Following is a breakdown of the most common issues found during surveys in the North Dakota CLIA program from Jan. 1, 2003, through Dec. 31, 2003.

- Comparison of Test Results — At least annually, laboratories must verify the accuracy of any test or procedure performed that is not included in Subpart I — Proficiency Testing Programs for Nonwaived Testing.

- Test Records — Records of patient testing, including, if applicable, instrument printouts, must be retained for at least two years.

- Quality Assessment — Laboratories must establish and follow written policies and procedures to monitor, assess and correct problems identified.

- Evaluation of Proficiency Testing Performance — Laboratories must review and evaluate the results obtained on proficiency testing.

- Following Manufacturer's Instructions — Laboratory testing must be performed following the manufacturer's instructions.

- Testing of Proficiency Samples — Proficiency testing samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.

Take a close look at your laboratory and identify if it is deficient in these areas; if so, take the corrective actions necessary to fix these areas prior to your next survey.

Key Terms

Quality System — All of the laboratory's policies, procedures, processes and resources needed to achieve quality testing

Quality Assessment — Replaces the term quality assurance. Quality Assessment is an ongoing review process that encompasses all facets of the laboratory's technical and nontechnical functions and all locations/sites where testing is performed.

Nonwaived — Replaces the terms moderate and high-complexity when referring to requirements that pertain to both levels of testing. (Moderate and high distinction still are applicable for personnel and test-method classification.)

Equivalent quality control (EQC) — Alternative control procedures

PLAN TO ATTEND

The North Dakota Department of Health's Division of Health Facilities CLIA survey staff will be presenting at the NDSCLS state meeting in April. There will be a session on The Basics of a Laboratory Survey and a session on Exploring the New CLIA Regulations.

Requirements for Transfusion Services

A facility that provides transfusion services is any entity that may store and/or administer blood and blood products to patients.

The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer and availability of blood and blood products.

The facility must provide prompt ABO and Rho typing, unexpected antibody detection, compatibility testing and laboratory investigation of transfusion reactions on a continuous basis through a CLIA-certified (or equivalent) laboratory. All transfusion related activities must be documented.

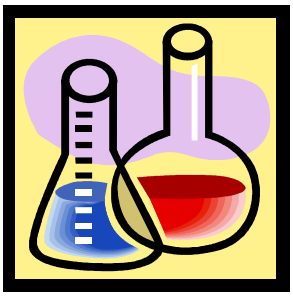
If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood-product. Temperatures need to be documented.

The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.

The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to federal and state authorities.

Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture

On Dec. 20, 2003, NCCLS published a revision to the document Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture (H3-A5). This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection and venipuncture in children. The major change is a revised order of draw. The document is available for purchase at www.nccls.org.



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North Dakota Department of Health
Division of Health Facilities
600 E. Boulevard Ave., Dept. 301
Bismarck, N.D. 58505-0200
Phone: 701.328.2352
Fax: 701.328.1890
Web: www.health.state.nd.us

Terry Dwelle, M.D., MPHTM, State Health Officer
Darleen Bartz, Chief, Health Resources Section
Bruce Pritschet, Director, Health Facilities
Bridget Weidner, Program Manager
Tanya Stebbins, CLIA Surveyor